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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,037	06/30/2005	Akinori Hanano	19036/40139	9381
4743 7590 04/21/2009 MARSHALL, GERSTEIN & BORUN LLP 233 SOUTH WACKER DRIVE 6300 SEARS TOWER CHICAGO, IL 60606-6357			EXAMINER STONE, CHRISTOPHER R	
			ART UNIT	PAPER NUMBER
			1614	
			MAIL DATE	DELIVERY MODE
			04/21/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/520,037

**Applicant(s)**

HANANO, AKINORI

**Examiner**

CHRISTOPHER R. STONE

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 5-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' arguments, filed September 16, 2008, have been fully considered but are moot in view of the new grounds of rejection. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Rosa et al (US 6,410,036 B1) in view of Tung et al (American Journal of Clinical Dermatology, 1(2), p. 81-88, 2000).

Claims 6, 7, 10 and 11 are drawn to an external composition comprising glycolic acid and polyvinyl alcohol and a method of chemically peeling the skin comprising contacting the skin with said composition.

De Rosa et al teaches an external composition comprising glycolic acid and polyvinyl alcohol useful as a chemical peeling agent. De Rosa et al further teaches applying the composition directly to skin (abstract, column 2, lines 57-61, column 3, lines 12-14 and column 24 lines 26-48). De Rosa et al does not explicitly teach the pH of the composition. Tung et al teaches that glycolic acid peel products having pH values

from 0.1-1.4 are useful in chemical peel procedures (p. 87, left column, 1st and 2nd paragraphs). Therefore it would have been obvious to one of ordinary skill in the art to prepare the composition of De Rosa et al at a pH of 1.4 or less to practice the method of Rosa et al comprising contacting skin with said composition, since this pH was known to be appropriate for chemical peel procedures, thus resulting in the practice of the instantly claimed composition with a reasonable expectation of success.

Claims 1, 5, 8, 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groh (US 5,863,943) in view of Tung et al (American Journal of Clinical Dermatology, 1(2), p. 81-88, 2000).

Claims 1, 5, 8, 9 and 12 are drawn to an external composition comprising glycolic acid and polyethylene glycol and a method of chemically peeling the skin comprising contacting the skin with said composition.

Groh teaches a composition comprising the alpha hydroxy acid, glycolic acid, and polyethylene glycol with a polymerization degree of 45,000, i.e. PEG 45M (column 2, lines 12-28 and Table 1). Groh teaches that said composition useful in the topical treatment of skin disorders which alpha hydroxy acids, such as glycolic acid, are known to treat (column 1, lines 7-54 and column 7, lines 20-22). Groh further teaches applying the composition directly to skin (claim 8). Groh et al does not teach al does not explicitly teach composition having a pH of 1.4 or less or a method of chemically peeling skin comprising contacting the skin with the composition. Tung et al teaches that glycolic acid peel products having pH values from 0.1-1.4 are useful in chemical peel procedures for the treatment of acne when applied directly to skin (p. 87, left column,

1st and 2nd paragraphs). Therefore it would have been obvious to one of ordinary skill in the art to prepare the composition of Groh at a pH of 1.4 or less and to practice method of chemically peeling the skin comprising contacting the skin with said composition, since this pH was known to be appropriate for chemical peel procedures in the treatment of acne and the composition of Groh was known to be useful in the treatment of conditions which glycolic acid is known to treat (e.g. acne), thus resulting in the practice of the instantly claimed composition with a reasonable expectation of success.

With regards to the alleged unexpected superior results (uniform application therefore uniform peeling) of the instantly claimed range of the degree of polymerization of polyethylene glycol (PEG), these results are not unexpected. As Applicant notes, PEGs with a degree of polymerization of 2000 or greater function as viscosity increasing agents and are provided as solids, whereas PEG with a lower degree of substitution function as humectants and have a liquid form (p. 5 of the Response to Non-Final Office Action, filed September 16, 2008). It is therefore expected that compositions comprising PEG with a higher degree of polymerization are more viscous and therefore are more amenable to an even distribution when applied to skin, as is observed in the declaration under 37 CFR 1.132, filed September 16, 2008. Additionally, it is noted that the composition of Groh, comprising PEG with a high degree of polymerization (including the instantly claimed 45,000) is in the form of a cream or lotion amendable for uniform application to the skin, as opposed to a liquid (column 4, lines 11-13 and column 7, lines 19-22).

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

16April2009  
CRS

/Patricia A. Duffy/  
Primary Examiner, Art Unit 1645